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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/579,314	05/16/2006	Urban Blomberg	P06,0128	8212
26574 7590 11/28/2007 SCHIFF HARDIN, LLP			EXAMINER	
PATENT DEPA 6600 SEARS T		LLOYD, EMILY M		
	CHICAGO, IL 60606-6473		ART UNIT	PAPER NUMBER
			3736	-
			MAIL DATE	DELIVERY MODE
			11/28/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

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	Application No.	Applicant(s)				
•	10/579,314	BLOMBERG ET AL.				
Office Action Summary	Examiner	Art Unit				
	Emily M. Lloyd	3736				
The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply						
A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION. - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication. - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).						
Status						
 1) ⊠ Responsive to communication(s) filed on 16 May 2006. 2a) ☐ This action is FINAL. 2b) ⊠ This action is non-final. 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213. 						
Disposition of Claims						
4) ☐ Claim(s) 20-37 is/are pending in the application 4a) Of the above claim(s) is/are withdray 5) ☐ Claim(s) is/are allowed. 6) ☐ Claim(s) 20,21,23 and 26-37 is/are rejected. 7) ☐ Claim(s) 22,24 and 25 is/are objected to. 8) ☐ Claim(s) are subject to restriction and/or	wn from consideration.					
Application Papers						
9) The specification is objected to by the Examine 10) The drawing(s) filed on is/are: a) accomplicated any not request that any objection to the Replacement drawing sheet(s) including the correct 11) The oath or declaration is objected to by the Examine	epted or b) objected to by the didaying(s) be held in abeyance. Section is required if the drawing(s) is ob	e 37 CFR 1.85(a). jected to. See 37 CFR 1.121(d).				
Priority under 35 U.S.C. § 119						
12) Acknowledgment is made of a claim for foreign a) All b) Some * c) None of: 1. Certified copies of the priority document 2. Certified copies of the priority document 3. Copies of the certified copies of the priority application from the International Bureau * See the attached detailed Office action for a list	s have been received. s have been received in Applicati rity documents have been receive u (PCT Rule 17.2(a)).	on No ed in this National Stage				
Attachment(s) 1) ☑ Notice of References Cited (PTO-892) 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 3) ☑ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date 05/16/2006.	4) Interview Summary Paper No(s)/Mail D 5) Notice of Informal F 6) Other:	ate				

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DETAILED ACTION

Drawings

- 1. The drawings are objected to because Figure 9 has the word "Yes," in it without a clear meaning as to what this indicates. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.
- 2. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they include the following reference character(s) not mentioned in the description: 20. Corrected drawing sheets in compliance with 37 CFR 1.121(d), or amendment to the specification to add the reference character(s) in the description in

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compliance with 37 CFR 1.121(b) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Specification

3. The disclosure is objected to because of the following informalities: the first paragraph of the specification should be a section titled "Cross-Reference to Related Applications" and should include a reference to the priority claimed, page 1 line 13 "the" should be inserted after "in", page 2 line 15 "is" is underlined, page 2 line 17 "electrodes" should be "electrodes", page 4 lines 26-27 contain underlined portions and should have the word "can" inserted between "electrodes" and "be" on line 26, page 5 line 2 it appears that "instead of" should be "instead for", page 6 line 12 should specify which country the parallel application was filed in, page 6 line 13 "figure" should be capitalized, page 7 line 1 it appears that "cut out" should be revised as the channels with the highest weighting factor are likely kept, page 7 line 19 should end with a period, page 7 lines 21-24 should be revised for clarity, page 8 line 25 "If there exist EMG-signals" should be revised (suggestion: "If EMG-signals exist"), page 9 lines 19 and 20

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"figures" should be capitalized, and page 10 line 8 the reference to Fig. 7 should instead refer to Fig. 9 (references are to the substitute specification).

Appropriate correction is required.

Claim Objections

4. Claims 20, 26, 32, and 33 are objected to because of the following informalities: claim 20 line 20, claim 26 line 29, and claim 32 line 7 "raw signal" should be "raw signals"; and claim 33 line 16 "normal" should be "normalize". Appropriate correction is required.

Claim Rejections - 35 USC § 112

- 5. The following is a quotation of the second paragraph of 35 U.S.C. 112:
 The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
- 6. Claims 27-31 and 33-37 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

As these claims depend on a device or computer readable medium and not a method, the reference to claims 20-22 and 24 is unclear. For the purpose of examination, the Examiner has interpreted these claims as depending from claims 26 and 32 in the same manner that claims 21-25 depend on claim 20, as follows: Claim 27 depends on claim 26, claims 28 and 29 depend on claim 27, claim 30 depends on claim 28, claim 31 depends on claim 30, claim 33 depends on claim 32, claims 34 and 35 depend on claim 33, claim 36 depends on claim 34, and claim 37 depends on claim 36.

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Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

8. Claims 20, 26, and 32 are rejected under 35 U.S.C. 102(e) as being anticipated by United States Patent 6901286 (Sinderby et al.).

Regarding claims 20, 26, and 32, Sinderby et al. disclose a method (Figure 4), a device (Figure 1), and a computer-readable medium encoded with a computer program loadable into a computer (personal computer 19 Figure 1 is inherently programmed with the method of Figure 4 in order to execute the method) for extracting an EMG signal out of a raw signal, said raw signal being obtained by a plurality of electrodes adapted to interact with a patient to capture signals from the diaphragm of the patient (array of electrodes 12 on diaphragm 11 Figure 1), each electrode having an associated signal channel in which a raw signal is received from the associated electrode (Figures 2 and

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3 each show 7 electrodes and 7 channels), said method comprising the steps of: for each of said channels, automatically electronically determining a signal-to-noise ratio for the raw signal in that channel (step 401 Figure 4, also Column 6 lines 23-31); for each of said channels, automatically electronically determining a weighting factor for that channel dependent on the signal-to-noise ratio of that channel; and weighting the respective raw signals from the channels by the respective weighting factors determined for the channels, to obtain weighted raw signals (step 405 Figure 4; also Column 7 line 40 – Column 8 52, especially Column 8 lines 51), and summing the weighted raw signal to obtain a summed signal representing a total EMG signal in said raw signals (step 408 Figure 4, also Column 11 lines 22-36). Sinderby et al. also disclose an analysis unit (personal computer 19 Figure 1) that performs the analysis steps.

Claim Rejections - 35 USC § 103

- 9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:
 - (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
- 10. The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:
 - 1. Determining the scope and contents of the prior art.
 - 2. Ascertaining the differences between the prior art and the claims at issue.
 - 3. Resolving the level of ordinary skill in the pertinent art.
 - 4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

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- 11. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).
- 12. Claims 21, 23, 27, 29, 33, and 35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sinderby et al.

Regarding claims 21, 27, and 33, Sinderby et al. disclose a method as claimed in claim 20, a device as claimed in claim 26, and a computer readable medium as claimed in claim 33 comprising, for each channel: automatically electronically estimating a level of ECG activity in the raw signal (Column 10 lines 36-42); automatically electronically estimating a level of EMG activity in the raw signal (Column 10 lines 36-42); automatically electronically determining said signal-to-noise ratio based on the estimated level of ECG activity and the estimated level of EMG activity (Column 10 lines 33-47).

Sinderby et al. do not expressly disclose normalizing said summed signal representing the total EMG signal. However, Sinderby et al. teach numerous calculations to represent the various features of the signal (Column 11 lines 23-28). It is well known in the art to calculate a normalized value of an output to allow for easier

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reference and comparison between various measurements of the same patient at different times and between different patients. It would have been obvious to one having ordinary skill in the art at the time the invention was made to use such a normalized summed signal representing the total EMG signal in the invention of Sinderby et al. to provide the predictable result of providing health care workers and ventilation systems with another measurement of EMG of the diaphragm that would provide for an easy reference.

Regarding claims 23, 29, and 35, Sinderby et al. teach a method as claimed in claim 21, a device as claimed in claim 27, and a computer readable medium as claimed in claim 33 comprising estimating the level of ECG activity by filtering an estimated ECG signal out of the raw signal (Column 6 lines 23-32, step 401 Figure 4) and comparing the estimated ECG signal with a threshold value (Column 7 lines 1-8, step 403 Figure 4).

Allowable Subject Matter

- 13. Claims 22 and 24-25 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.
- 14. Claims 28, 30-31, 34, and 36-37 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.
- 15. The following is a statement of reasons for the indication of allowable subject matter: the limitation of calculating the signal-to-noise ratio according to the equation

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 $R^{n}/(R + S)$ where R is the estimated level of EMG activity, S is the estimated level of ECG activity, and n is an integer greater than 1 is not found in the prior art.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Emily M. Lloyd whose telephone number is 571-272-2951. The examiner can normally be reached on Monday through Friday 8:30 AM - 5 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on 571-272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have guestions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

> Emily M Lloyd Examiner Art Unit 3736

/EML/